

**Amendments to the Drawings:**

The attached sheet of drawings that is labeled “New Sheet” includes new Figs. 16 and 17.

### **REMARKS/ARGUMENTS**

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. Claims 1-14 are pending, with 1 and 8 being the independent claims. Claims 1, 3, 8 and 9 are sought to be amended. Amendments to the specification are sought to be made, as well as the addition of new FIGS. 16 and 17. The proposed amendment places the claims in condition for allowance or in better form for appeal. Additionally, this amendment addresses items brought up by the Examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

#### **Drawing Objections**

The drawings are objected to under 37 CFR § 1.83(a) as not showing every feature of the claims. Particularly, the Examiner noted that the feature “a guide member slidably coupled to the [shaft] for providing access to the guidewire lumen via the longitudinal cut” of claims 1 and 9 must be shown or the feature canceled from the claims. Applicant includes herewith a new sheet of drawings with new FIGS. 16 and 17 that show the aforementioned feature. FIGS. 16 and 17 are essentially FIGS. 7 and 14, respectively, of U.S. Patent No. 6,800,065 to Duane et al., which issued from U.S. Appl. No. 10/116,234. The ‘234 application was incorporated by reference in its entirety into the present application as filed, as noted in paragraph [0015] of the specification. Thus no new matter is introduced with the addition of FIGS. 16 and 17 to the present specification.

#### **35 U.S.C. §112 Rejections**

The Examiner rejected claims 1 and 9 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner found the limitation “a guide member slidably coupled to the [shaft] for providing access to the guidewire lumen via the longitudinal cut” of claims 1 and 9 to be vague. The Examiner interpreted this feature to be a guidewire. *See* Office Action p. 3.

Applicant has addressed the indefiniteness rejection of claims 1 and 9 by providing new FIGS. 16 and 17, as noted in the preceding section. In addition, Applicant has amended

the specification to include description of new FIGS. 16 and 17. The material added to describe FIGS. 16 and 17 is essentially the description of FIGS. 7 and 14, respectively, of U.S. Patent No. 6,800,065 to Duane et al., which issued from U.S. Appl. No. 10/116,234 that was incorporated by reference as discussed above. Thus no new matter is introduced with the addition of FIGS. 16 and 17 and the corresponding description thereof to the present specification.

35 U.S.C. §103(a) Rejections

Claims 1-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,004,310 to Bardsley et al. in view of U.S. Patent No. 4,988,356 to Crittenden et al. and/or U.S. Patent No. 3,972,529 to McNeil.

The Examiner's obviousness rejection of independent claims 1 and 8 states that Bardsley discloses a catheter having "a proximal shaft defining a guide wire lumen 110; and inflation lumen 120; ... a support strip/reinforcement member/joint member 135 or 225 or 330 (see Figs. 2-5) [and] a guide member (guide-wire) slidably coupled to the proximal shaft." Office Action, p. 3. The Examiner also states that "the element 135 can be a plank-like support strip or joint member [and] may be of a variety of different configuration designed, (such as a plank-like support strip or joint member) to impart the desired stiffness to the catheter shaft section and prevent kinking ... (col. 6, lines 14-20)." Office Action pp. 3-4. The Examiner also states that "Applicant admitted that it is well-known in the art that the reinforcement means [is] provided in [the] catheter shaft in order to reinforce the proximal shaft (Specification, para [0056])." Office Action p. 4.

Applicants traverse the Examiner's rejection of claims 1 and 8, as Bardsley et al. does not teach, *inter alia*, a plank-like or plate-like support strip or a guide member. As an initial matter, a guide member, as recited in claim 1, is not a guidewire and Applicants have supported this feature of the claim with new FIGS. 16 and 17, as well as with written description, to address the Examiner's uncertainty as to this element. Bardsley et al. has a full-length reinforced guidewire lumen and does not teach or suggest using a guide member therewith.

As discussed in Applicants' Amendment filed January 17, 2008, Bardsley et al. teaches a **tubular** support member (135, 225, 330, 535, 635) for maintaining the **circular**

cross-section of the guidewire lumen to prevent distortion and possible closing-off or kinking of the guidewire lumen during operation. *See* Bardsley et al., col. 1, lines 50-53; col. 2, lines 13-31; col. 5, lines 7-11; col. 6, lines 14-20; col. 6, line 66- col. 7, line 4; col. 7, lines 29-33; and col. 8, lines 59-65; FIGS. 2-5, 7 and 8. The Examiner interprets the statement in col. 6, lines 14-20 of Bardsley et al. to render obvious “a plank-like support strip” as recited in claim 1 and “plate-like support strips” as recited in claim 8; however, this is an overly broad interpretation of only a portion of that passage which actually reads in its entirety:

support member **135** may be of different materials and configurations designed to impart the desired stiffness to the catheter shaft **and in particular ensure that the cross-sectional shape of the lumen** remains substantially undistorted as [it] undergoes the high flexure encountered during traversal of the sharp bends in the vascular pathway.

(Emphasis added). The support member (135) is necessarily **concentrically** disposed about the guidewire tube (130) to provide maximum integrity to guidewire lumen (110) while traversing the tortuous vasculature. *See* Bardsley et al., col. 6, lines 56-63; FIG. 2. In contrast, the support strip of claims 1 and 8 is recited as “plank-like” or “plate-like” to clarify its structure as a **nontubular** strip of material that is radially disposed within a wall of the shaft between the guidewire lumen and an outer surface, as such the support strip is clearly recited **to extend along only one side of the guidewire lumen and is also recited to be proximate the longitudinal cut**. The structure and position of the plank-like/plate-like support strips of claims 1 and 8 is not taught or suggested by the tubular support member of Bardsley et al., as it would not achieve the stated function of Bardsley et al. of ensuring the cross-sectional shape of the guidewire lumen as the catheter is traversed through the tortuous vasculature. Further, the Examiner stated that Applicants’ paragraph [0056] of the present specification renders “a plank-like support strip” obvious, yet that paragraph only refers to **tubular** reinforcement means that may be “*inserted* into a guidewire lumen or inflation lumen,” as conventional and not to a support strip according to any of the claims of the present application.

The Examiner relies on Crittenden et al. as disclosing a longitudinal cut extending radially from an outer surface of the shaft to the guidewire lumen. The Examiner states that it would have been obvious “to modify the device of Bardsley et al. with a longitudinal cut,

as taught by Crittenden, in order to provide a means for inserting and removing an object, such as a guide wire.” Office Action p. 4. Applicants contend that the proposed modification of Bardsley et al. in view of Crittenden et al. would make the multilumen catheter shaft of Bardsley et al. unfit for its intended purpose such that one of ordinary skill in the art would not find it obvious to make the proposed modification. Bardsley et al. teaches **fortifying the guidewire lumen** by encircling or surrounding the lumen with a tubular support member (135), which ensures the integrity of the cross-sectional shape of the lumen and prevents the lumen walls from being distorted or deflected against the guidewire during an interventional procedure. *See* Bardsley et al., col. 6, lines 14-20; col. 6, line 56-col. 7, line 2. The Examiner’s suggested addition of a longitudinal cut through the shaft wall of the catheter of Bardsley et al. to the guidewire lumen (110) would result in the tubular support member (135) being cut too, thereby eliminating or drastically diminishing any reinforcement or support benefit that support member (135) was to provide the lumen. Thus, one of ordinary skill in the art would not find it obvious to modify the catheter of Bardsley et al. with a longitudinal cut as disclosed in Crittenden et al. For the foregoing reasons, Applicants contend that claims 1 and 8 are patentable over the disclosure of both the Bardsley et al. and Crittenden et al. patents, taken alone or in combination.

Claims 2-7 that depend from and add further features to independent claim 1 and claims 9-14 that depend from and add further features to independent claim 8 are patentable for that reason alone. However while it is not necessary to address the Examiner’s rejection of the dependent claims at this time, Applicants reserve the right to support their patentability, when necessary.

At this time though, Applicants will address the Examiner’s statement that he is not differentiating structure between “reinforcing means 435, support strip, and joint member” stating that they are the “same element with different names and shapes.” Office Action p. 5. The Examiner is correct that each of the *plank-like/plate-like* support strips and the *curved* reinforcement member reinforces, but it is the shape and positioning in a particular portion of the longitudinally cut shaft that distinguishes one from the other. The Examiner is incorrect as to a joint member, which is not a reinforcement but instead is for “[m]odifying the bending stiffness of [the] extruded shaft **128** in areas around the guidewire lumen ... so that

the ability to open longitudinal cut **134** can be maintained.” Specification ¶ [0061]. The use of the combination of *plank-like/plate-like* support strips on either side of the longitudinal cut, a *curved* reinforcement member and/or a joint member provides a beneficial combination of properties to a longitudinally cut proximal shaft according to claims hereof. As such, the Examiner’s reliance on McNeil is off-point and irrelevant to a joint member that permits bending of the catheter shaft and opening of the longitudinal cut, as amended in the present claims, as McNeil teaches ***increasing strength*** and ***stiffness*** of an aluminum ***golf club shaft*** by adding graphite strips within longitudinal recesses cut into the shaft. McNeil, col. 1, lines 3-5 and lines 56-64; col. 2, lines 6-9. The Examiner statement that “[i]t is noted that the catheter device is well-known formed of lightness of weight and need high strength to prevent kinking when inserted into the body/vessel” ignores the fact that although the catheter shaft must have columnar strength for pushability it must also retain its flexibility in order to be navigated through the tortuous anatomy. Office Action p. 4. As such, one of ordinary skill in the art would not find the graphite strips of McNeil desirable or to render obvious a joint member according to the claims hereof.

In view of the amendments and arguments above, Applicants believe claims 1-14 are patentable over Bardsley et al, Crittenden et al. and/or McNeil alone or in combination and are in condition for allowance.

**Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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